

WHAT IS CLAIMED IS:

- 1 1. A method for inactivating a pathogen in a protein solution which
2 comprises adding to said protein solution either separately or together:
3 (a) a detergent; and
4 (b) an ester of a carboxylic acid formed between a carboxylic acid selected
5 from the group consisting of monocarboxylic acids, dicarboxylic acids
6 and tricarboxylic acids, and an alcohol which is a member selected
7 from monohydroxy alcohols, polyhydroxy alcohols, and combinations
8 thereof, to make a preparation, said ester being present in said
9 preparation in a concentration of from about 0.001% to about 2%
10 (w/w) and said detergent being present in a concentration of from
11 about 0.001% to about 2 % (w/w);
12 and incubating said preparation for an amount of time sufficient to inactivate
13 said pathogen.
14
1 2. The method according to claim 1 wherein said carboxylic acid is a
2 member selected from the group consisting of hydroxy-monocarboxylic acids, hydroxy-
3 oligo-carboxylic acids, keto-monocarboxylic acids, keto-oligocarboxylic acids and
4 combinations thereof.
5
1 3. The method according to claim 1 wherein said alcohol is a member
2 selected from the group consisting of ethanol, n-butanol, dodecanol, tetradecanol,
3 hexadecanol, octadecanol, eicosanol, glycerol, threitol, erythritol, pentitols and hexitols,
4 pentose or hexose monosaccharide, and pentose or hexose oligosaccharide.
5
1 4. The method according to claim 1 wherein said alcohol is a short chain
2 alcohol.
3
1 5. The method according to claim 1 wherein said carboxylic acid is a
2 member selected from the group consisting of acetic acid, butyric acid, adipic acid, sebacic
3 acid, succinic acid, and fumaric acid.
4
1 6. The method according to claim 1 wherein said ester is a member
2 selected from the group consisting of mono-, di- and triglycerides of short chain fatty acids.

1 7. The method according to claim 6 wherein said ester is a member
2 selected from the group consisting of monoacetyl glycerides, diacetylglycerides,
3 triacetylglycerides, monobutyryl glycerides, dibutyrylglycerides, and tributrylglycerides.

1 8. The method according to claim 2 wherein said carboxylic acid is a
2 member selected from the group consisting of lactic acid, glycolic acid, malic acid, tartaric
3 acid, monoacetyl tartaric acid, diacetyl tartaric acid, citric acid, isocitric acid, and gluconic
4 acid.

1 9. The method according to claim 1 wherein said ester is selected from
2 the group of citric acid esters consisting of triethyl citrate, tributyl citrate, and acetyl
3 triethyl citrate.

1 10. The method according to claim 2 wherein said carboxylic acid is a
2 member selected from the group consisting of pyruvic acid and oxaloacetic acid.

1 11. The method according to claim 1 wherein said detergent is a member
2 selected from the group consisting of an alkali metal salt of a fatty acid, a cholic (bile) acid, a
3 sodium- or calcium stearyl lactyl 2-lactate, a short-chain ($< C_{14}$) fatty acid monoglyceride, a
4 short-chain ($< C_{14}$) fatty acid diglyceride, sugar fatty acid esters, sugar glycerides, sorbitan-
5 fatty acid esters, sorbitan-polyoxyethylene-fatty acid esters (polysorbates), and octoxynol 9
6 (triton X-100), nonoxynol 9 and combinations thereof.

1 12. The method according to claim 1, wherein said detergent is a member
2 selected from the group consisting of a fatty acid monoglyceride which is esterified with a
3 member selected from acetic acid, lactic acid, citric acid, tartaric acid, monoacetyl tartaric
4 acid, diacetyl tartaric acid and combinations thereof; and a fatty acid diglyceride which is
5 esterified with a member selected from acetic acid lactic acid, citric acid, tartaric acid,
6 monoacetyl tartaric acid, diacetyl tartaric acid and combinations thereof.

1 13. The method according to claim 11 wherein said detergent is Tween 80.

1 14. The method according to claim 1 wherein the concentration of said
2 ester in said preparation is from about 0.01% to about 1 % (w/w).

1 **15.** The method according to claim **14** wherein the concentration of said
2 ester in said preparation is from about 0.1% to about 0.5 % (w/w).

1 **16.** The method according to claim **1** wherein the concentration of said
2 detergent is from about 0.5% to about 1 % (w/w).

1 **17.** The method according to claim **1** wherein said preparation is incubated
2 for at least about 0.5 min.

1 **18.** The method according to claim **1** wherein said preparation is incubated
2 at a temperature from about 0 °C to about 60 °C

1 **19.** The method according to claim **1** wherein said protein is enriched from
2 a natural source by chromatographic or precipitation methods.

1 **20.** The method according to claim **1** wherein said protein is a member
2 selected from the group consisting of a recombinantly produced protein and a transgenically
3 produced protein.

1 **21.** The method according to claim **1** wherein said protein is a member
2 selected from the group consisting of plasma, coagulation factors, immunoglobulin, albumin,
3 antithrombin III, Cl-esterase inhibitor, α_1 -antitrypsin (α_1 -proteinase inhibitor) and FEIBA.

1 **22.** The method according to claim **1**, wherein said coagulation factor is a
2 member selected from factor IX, and factor X.

1 **23.** The method according to claim **1** wherein said pathogen is a lipid-
2 enveloped virus.

1 **24.** The method according to claim **23** wherein said pathogen is a member
2 selected from the group consisting of Hepatitis virus, human immunodeficiency virus, bovine
3 viral diarrhoea virus, herpes virus, and pseudorabies virus and combinations thereof.

1 **25.** A method for enhancing the pathogen inactivating properties of a
2 composition comprising at least one detergent said method comprising adding to said
3 composition a carboxylic acid ester formed between a carboxylic acid selected from the
4 group consisting of monocarboxylic acids, dicarboxylic acids and tricarboxylic acids, and an

alcohol which is a member selected from monohydroxy alcohols, polyhydroxy alcohols, and combinations thereof.

26. The method according to claim 25 wherein said ester is added to said composition in a concentration of from about 0.001% to about 20 % (w/w).

27. The method according to claim 26 wherein said ester is added to said composition in a concentration of from about 0.1% to about 10 % (w/w).

28. The method according to claim 27 wherein said ester is added to said composition in a concentration of from about 2% to about 5 % (w/w).

29. The method according to claim 25 wherein said detergent is present in said composition in a concentration of from about 0.01% to about 20 % (w/w).

30. The method according to claim 29 wherein said detergent is present in said composition in a concentration of from about 5% to about 10 % (w/w).

31. The method according to claim 25 wherein said carboxylic acid is a member selected from the group consisting of hydroxy-monocarboxylic acids, hydroxy-oligo-carboxylic acids, keto-monocarboxylic acids, keto-oligocarboxylic acids and combinations thereof.

32. The method according to claim 25 wherein said alcohol is a member selected from the group consisting of ethanol, n-butanol, dodecanol, tetradecanol, hexadecanol, octadecanol, eicosanol, glycerol, threitol, erythritol, pentitols and hexitols, pentose or hexose monosaccharide, and pentose or hexose oligosaccharide.

33. The method according to claim 25 wherein said alcohol is a short chain alcohol.

34. The method according to claim 25 wherein said carboxylic acid is a member selected from the group consisting of acetic acid, butyric acid, adipic acid, sebacic acid, succinic acid, and fumaric acid.

35. The method according to claim 25 wherein said ester is a member selected from the group consisting of mono-, di- and tri-glycerides of short chain fatty acids.

1 **36.** The method according to claim **35** wherein said ester is a member
2 selected from the group consisting of monoacetyl glycerides, diacetylglycerides,
3 triacetylglycerides, monobuteryl glycerides, dibutrylglycerides, and tributrylglycerides.

1 **37.** The method according to claim **31** wherein said carboxylic acid is
2 selected from the group consisting of lactic acid, glycolic acid, malic acid, tartaric acid,
3 mono- and diacetyl tartaric acid, citric acid, isocitric acid, and gluconic acid.

1 **38.** The method according to claim **31** wherein said ester is selected from
2 the group of citric acid esters consisting of triethyl citrate, tributyl citrate, and acetyl triethyl
3 citrate.

1 **39.** The method according to claim **31** wherein said carboxylic acid is
2 selected from the group consisting of pyruvic acid and oxaloacetic acid.

1 **40.** The method according to claim **25** wherein said detergent is a member
2 selected from the group consisting of an alkali metal salt of a fatty acid, a cholic (bile) acid, a
3 sodium- or calcium stearyl lactyl 2-lactate, a short-chain (< C14) fatty acid monoglyceride,
4 a short-chain (< C14) fatty acid diglyceride, sugar fatty acid esters, sugar glycerides, sorbitan-
5 fatty acid esters, sorbitan-polyoxyethylene-fatty acid esters (polysorbates), and octoxynol 9
6 (triton X-100), nonoxynol 9 and combinations thereof.

1 **41.** The method according to claim **25**, wherein said detergent is a member
2 selected from the group consisting of a fatty acid monoglyceride which is esterified with a
3 member selected from acetic acid, lactic acid, citric acid, tartaric acid, monoacetyl tartaric
4 acid, diacetyl tartaric acid and combinations thereof; and a fatty acid diglyceride which is
5 esterified with a member selected from acetic acid lactic acid, citric acid, tartaric acid,
6 monoacetyl tartaric acid, diacetyl tartaric acid and combinations thereof.

1 **42.** The method according to claim **40** wherein said detergent is Tween 80.